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VENTILATOR MASK AND SYSTEM

### CROSS-REFERENCE TO PRIORITY APPLICATION

[0001] This application claims the benefit of U.S. Provisional Application No. 60/505,718, filed September 25, 2003, the content of which is incorporated herein by reference in its entirety.

### BACKGROUND OF THE INVENTION

#### 1. Field of The Invention

[0002] The present invention relates to ventilators, e.g., continuous positive air pressure ("CPAP") systems comprising a mask and an air flow generator, wherein the air flow generator is mountable to the mask's wearer. In one embodiment, the present invention provides CPAP systems wherein an air flow generator is mounted on the mask. In other embodiments, the air flow generator may be provided to the body of the wearer, e.g., the arm, leg, chest or waist, and a short air delivery tube can be used to connect the mask with the air flow generator.

#### 2. Description of Related Art

[0003] CPAP administration is commonly used to treat respiratory conditions such as obstructive sleep apnea. The procedure for CPAP administration typically involves sealingly engaging a mask over a patient's nasal and/or oral region and supplying pressurized air to a chamber formed by the interior of the mask. In conventional systems, the air is supplied to the mask by an air flow generator typically placed in proximity to the patient's bed. An air delivery tube is thus needed to deliver air generated by the air flow generator to the mask.

[0004] There are two main sources of instability of a mask system during use or sleep. Normal patient movement can create instability, for example, a patient rolling on his or her side, which may cause the mask to interfere with the bedding material. Another concern of using an air delivery tube that is connected to an apparatus away from the patient is so-called "tubing drag", which refers to a drag force on the air delivery tube which is draped over the back or side of the bed. Tubing drag can be created or complicated by movement of the wearer. Tubing drag may cause relative movement between the mask seal and the patient's face during the CPAP administration and produce leaks and/or discomfort.

[0005] Another concern involving the air delivery tube is the length thereof (often about 2 meters or more), which may impart a lag in the response and rise times in delivering pressured air from the air flow generator to the mask. Increased flow impedance and/or pressure drop due to diameter and length of tubing may also necessitate a larger blower motor to compensate for the pressure drop along the air delivery tube.

[0006] U.S. Patents 4,590,951; 5,372,130; and 6,435,184 describe masks for safety applications.

#### SUMMARY OF THE INVENTION

[0007] Aspects of the present invention include addressing the concerns in the art, e.g., by reducing or eliminating the risk of tubing drag during CPAP administration.

[0008] A further aspect of the present invention is to provide the wearer with a greater freedom of movement in bed without compromising seal and/or comfort.

[0009] Another aspect of the present invention includes reducing or eliminating the lag in response/rise times in delivering pressured air from the generator to the mask.

[0010] In one embodiment, a ventilator or CPAP system comprises a mask and an air flow generator, wherein both the mask and the air flow generator are provided to or on the wearer. In one embodiment, the mask is configured to be fitted to the patient's face and the air flow generator is mountable to the wearer's body. The air flow generator may be provided directly to the mask.

[0011] According to one embodiment a CPAP system comprises a face mask and an air flow generator, wherein the air flow generator is mounted on the face mask.

[0012] In a further embodiment, a ventilator or CPAP system comprises:

- (i) a face mask configured to be placed over an area of a wearer's face, the face mask having:
  - (1) a shell;
  - (2) a cushion provided to a perimeter of the shell to sealingly connect the face mask to the area of a wearer's face and thereby form a chamber between the shell and the wearer's face; and
  - (3) an inlet port in the shell to receive a flow of breathable gas;
- (ii) an air flow generator, said air flow generator being mounted on said mask and being capable of creating a pressure of about 2-40cm H<sub>2</sub>O in the chamber.

[0013] In embodiments, a ventilator or CPAP system includes an air flow generator able to be located sufficiently close to a wearer so that an air delivery tube may be less than 1.5 meters in length.

[0014] In one embodiment, a ventilator or CPAP system comprises:

a face mask having an inlet port,  
an air flow generator having an outlet, and  
at least one air delivery tube for delivering breathable gas from the gas outlet to the inlet port,

wherein the at least one air delivery tube does not exceed about 1.5 meters in length. The at least one air delivery tube may include two or more air delivery tubes having a combined overall length of not more than about 1.5 meters.

[0015] In a further embodiment, a ventilator or CPAP system comprises:

- (i) a face mask having
  - (1) a shell;
  - (2) a cushion provided to the shell to sealingly connect the face mask to a wearer's face and thereby form a chamber between the shell and the wearer's face, and;
  - (3) an air inlet port in the shell to receive a flow of breathable gas;
- (ii) an air flow generator; and
- (iii) an air delivery tube not exceeding 1.5 meters in length, the air delivery tube being functionally connected to the air inlet port and the air flow generator to create a pressure of about 2-40cm H<sub>2</sub>O in the chamber by delivery of breathable gas from the air flow generator to the air inlet port.

[0016] Additional aspects, advantages and features of the present invention are set forth in this specification, and in part will become apparent to those skilled in the art on examination of the following, or may be learned by practice of the invention. The inventions disclosed in this application are not limited to any particular set of or combination of aspects, advantages and features. It is contemplated that various combinations of the stated aspects, advantages and features make up the inventions disclosed in this application.

#### BRIEF DESCRIPTION OF THE DRAWINGS

- [0017] Figure 1 is a perspective view of a CPAP system according to one embodiment of the invention;
- [0018] Figure 2 is an exploded view of the CPAP system of Figure 1;
- [0019] Figure 3 is a front view taken from an interior of the CPAP system of Figure 1;
- [0020] Figure 4 is a rear view taken from an exterior of the CPAP system of Figure 1;
- [0021] Figure 5 is a right side view of the CPAP system of Figure 4;
- [0022] Figure 6 is a top view of the CPAP system of Figure 4;
- [0023] Figure 7 is a bottom view of the CPAP system of Figure 4;
- [0024] Figure 8 is a bottom view of a CPAP system according to a further embodiment of the invention;
- [0025] Figure 9A illustrates a person wearing the CPAP system of Figure 1;
- [0026] Figure 9B illustrates an alternative embodiment of the present invention;

[0027] Figure 10A illustrates a person wearing a CPAP system according to a further embodiment of the invention;

[0028] Figure 10B is a schematic view of an air flow generator and battery pack for a CPAP system according to an embodiment of the invention;

[0029] Figure 11A represents a person wearing a CPAP system according to a further embodiment of the invention; and

[0030] Figure 11B represents a battery pack and strap for a CPAP system according to an embodiment of the invention.

#### DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0031] A CPAP system includes a mask and an air flow generator, wherein the air flow generator is provided to a wearer of the mask. In one embodiment, the air flow generator is mountable to a wearer's body (including a wearer's clothing). In another embodiment, the air flow generator is mounted on or provided to the mask.

[0032] Figures 1-11B show several embodiments of CPAP systems according to the present invention.

[0033] Referring to Figure 1, a CPAP system 10 includes a mask 60 provided with a cushion 30 and a shell 46 to form an air chamber in communication with the airways of a wearer. In this example, the mask 60 covers at least the oral and nasal region of a wearer. However, the mask 60 could also be a nasal mask and cover, for instance, only the nasal region or only the mouth region. In either case, it is preferable that the mask does not cover or interfere with the wearer's eyes or vision. The mask may include a vent opening 61 for CO<sub>2</sub> gas/washout, and one or more inlet

ports 47 for use in introducing supplemental gas, e.g., oxygen, into the air chamber.

The vent opening 61 can be covered with a suitable insert 63 or the like to controllably exhaust CO<sub>2</sub>. The insert is described in ResMed's U.S. Patent Nos. 6,561,190 and 6,561,191, each incorporated herein by reference in its entirety.

[0034] Mask cushion 30 is preferably made of a soft material (e.g. a rubber material, such as a silicone elastomer) and sealingly connects to the wearer's face to form the air chamber between the wearer's face and the mask 60. The shell can be made of a relatively hard plastic, although the shell can be made of the same material as the cushion 30, in some applications. Examples of cushions 30 are described in, for instance, U.S. Patent 6,513,526, assigned to ResMed Limited, which is hereby incorporated in its entirety by reference. Commercial examples of mask 60 include, for instance, the Mirage® Full Face Mask Series II from ResMed Limited (not taking into account adjustments described below in more detail).

[0035] Headgear connectors 50 are provided to the shell 46. Headgear connectors are designed to receive headgear straps for securing CPAP system 10 to a wearer's head (securing straps 55 are shown in Figures 9 and 10A). Attached to shell 46 is an extension 72 which will generally be provided with a resilient pad (not shown) to engage the forehead of the wearer, to provide additional stability. A strap may be provided to each connector 50 of the extension 72 for contact with the wearer's crown. Alternatively, or in addition, a strap connector 50a may be provided to the extension 72 such that the strap extends over the top of the wearer's head, as shown in Figures 9 and 10A.

[0036] The air chamber formed between a wearer's face and the interior of mask 60 receives breathable gas (e.g. air) through air inlet port 56 (see Figure 2), which is designed to be placed in close proximity to (e.g. over) the wearer's oral/nasal region. The breathable gas is supplied by air flow generator 20. In one embodiment, the air flow supplied by air flow generator 20 creates single or variable pressures within the air chamber in the range of 2-40 cm H<sub>2</sub>O, for instance 10-28 cm H<sub>2</sub>O or 15-20 cm H<sub>2</sub>O; or relatively constant 10 cm H<sub>2</sub>O etc.

[0037] Referring to Figure 2, air flow generator 20 includes, for example, a first part 90 and a second part 80 that are joined, e.g., by screws 130 through bores 134 and 136 to form a housing for impeller 120 and motor 100. The parts 80 and 90 may be made from a variety of materials, for instance from cured resinous materials, from metal (e.g. aluminum), or from polymers, e.g. from polyolefins (such as polyethylene or polypropylene), polycarbonates, or acrylonitrile-butadiene-styrene polymers ("ABS").

[0038] Motor 100 drives impeller 120. Power is supplied to motor 100 via power cord 110 and the motor is fixedly secured within the impeller housing by tightening screw 132. Examples of electrical motors include, for instance, miniature bullet motors commercially available from, e.g., Servo Magnetics Inc., of California. However, various types of motors may be used, including for instance pneumatic air powered motors in which case the energy source would be a tiny air line instead of an electrical pulse. The motor assembly may include multiple motors or single motors with multiple impellers, double ended impellers, etc. Other possibilities include separate systems which can deliver prescribed air pressure. In another variant,



another motor impeller assembly can be utilized to modify, for instance, if an inflatable cuff is provided to react to stimulus or sensed parameters like leak problems. A separate motor impeller can be used to control positioning of the mask relative to the face or the profile of the cushion seal.

[0039] Examples of impellers include, for instance, the S6 CPAP impeller from ResMed Limited. Various impellers may be used, however, such as axial fans, radial fans, centrifugal fans, etc. or any new technology able to deliver the required flow of gas such as air.

[0040] The power cord 110 may receive power from any suitable power source, e.g., a wall power outlet, wall mounted transformers, a battery pack or other power storage medium. In one embodiment, power cord 110 includes sensor cables to register and/or adjust to data received from sensors that may be provided in the mask (e.g. CO<sub>2</sub>, O<sub>2</sub>, humidity, pressure, flow, and/or temperature sensors). In one embodiment, the monitoring of sensors occurs via infrared technology or radio waves. A control box may be provided to adjust, e.g., the motor speed, e.g., for bi-level treatment, or other parameters relative to the information received through the sensors. Other embodiments may be to sense leak and adjust motor speed and thus delivery pressure or flow accordingly.

[0041] The power cord 110 can be connected to a small controller chip (not shown) integrated with an electrical transformer plugged into a power outlet. This provides greater flexibility, freedom of movement of the wearer, increased versatility during traveling, etc. Also, there are less components at the mask interface, less overall size of the system and potentially greater stability. The system may be used

for bi-level treatment or general ventilatory applications, e.g., where the magnitude of the pressurized air varies. The system may also provide faster response and rise times and eliminate or at least reduce lag associated with air delivery tubes typically having a length of 2m or more. The system may be easier to use from the perspective of a physician, a dealer or clinician, in that only one rather than numerous components need to be fitted for the wearer.

[0042] Another embodiment provides the ability to change the strap adjusting points; the ability to modify the fit of the mask relative to the face through the integrated sensing. For example, if there is a leak generated by the mask and a sensor, e.g., a pressure transducer 67 (Figure 4), produces a signal indicative of leaking in the mask, the flow generator pressure could be modified. There is also an embodiment where bladders or cuffs or sections of the mask seal could be modified so that the seal profile is modified in certain regions until the leak is resolved and the sensors would provide feedback to the control box that the leak is gone and the motor can be controlled to react to the feedback. See, e.g., U.S. Patent Application No. 10/332,578 filed December 19, 2002, to ResMed, incorporated herein by reference in its entirety.

[0043] Sensing flow or pressure of the mask system will increase reaction time and having a motor and an impeller assembly mounted directly into a mask system would mean that reaction times to pressure and flow changes would be very rapid; therefore there is improved synchrony of delivered gas to the wearer. Presently, flow generators essentially need to predict when a patient is about to breathe in or have some delay or lag, for example, by pressure sensors mounted to the flow generator. By contrast, one aspect of the present embodiment allows the mask system to react

very quickly, which provides excellent synchrony of the flow to a patient and this is key to treat patients especially those with respiratory insufficiency who require very good synchrony of flow generator flow pattern to a breathing patient.

[0044] Air flow generator 20, e.g., second part 80, is mounted on mask 60, e.g., with four screws 140 (only two are shown in Figure 2) which extend through holes 70 (also, only two shown) into bores 136 (at the opposite side of screws 130). Of course, a variety of other methods for mounting the air flow generator 20 on full face mask 60 are feasible, such as using adhesives, using melt-welding, or integrally forming the shell 46 and second part 80 through injection molding. Still another embodiment includes the ability to easily remove the generator 20 from the mask, e.g., to facilitate cleaning, etc. One or more quick release clips could be used for this purpose.

[0045] In one embodiment, such as the embodiment shown in Figure 2, a perforated screen 40 (e.g. a perforated metal screen, for instance a perforated aluminum screen) is placed between inlet port 56 and air flow generator 20. The screen separates the outlet 85 (Fig. 3) from air flow generator 20 and prevents foreign matter that might enter the air flow generator from reaching the wearer's oral and facial region (air outlet 85 is visible in Figure 3 through screen 40). Perforated screen 40 also ensures that a wearer's tongue or other body parts larger than perforation size cannot contact the impeller 120. Examples of perforated screen 40 include, for instance, a mesh structure or a thin plate with a plurality of small bores. This arrangement also prevents any motor or impeller failure such as breakage from harming the wearer.

[0046] Figures 3-7 show various views for the CPAP mask 10 in Figures 1 and 2. A further embodiment is depicted in Figure 8, where a filter 128 is provided in front of air intake opening 125 (See Figure 7 for air intake opening 125). The filter 128 may be, for instance, a filter to prevent dust from entering the impeller system (i.e. a dust filter) or a perforated screen. Although a perforated screen does not prevent dust from entering the impeller system, it is helpful in avoiding, for instance, the wearer's fingers from being able to come into contact with the impeller 120. In addition, a perforated screen prevents larger particles from entering the impeller system. In one embodiment, the CPAP system and/or the air flow generator has a dust or antimicrobial filter. In a further embodiment, the CPAP system and/or air flow generator is absent a dust or antimicrobial filter.

[0047] Referring to Figure 9A, the CPAP system of Figure 1 is mounted on the face of a wearer 1 by means of strap 55. The power is provided to the air flow generator 20 by battery pack 150 via power cord 110. Battery pack 150 is attached to the wearer's body via strap 160. Advantages of using a battery pack as the power source include, for instance, the increased mobility of the wearer. In yet another embodiment illustrated in Figure 9B, power to the air flow generator may be provided via a transformer power pack 150' plugged into a wall outlet 163.

[0048] Figure 10A shows an embodiment where impeller system 20A is not directly mounted on mask 60A but instead on a wearer's body via strap 160. The air outlet of air flow generator 20A is attached to air delivery tube 65, which is connected to the air inlet port of full face mask 60A via socket 64 and coupling tube 62. In one embodiment, air delivery tube 65 is shorter than 1.5 meter, for instance 1.0 meter or

0.5 meter. The air delivery tube may be of any diameter or include multiple air tubes that are low profile and/or kink resistant, as described in ResMed's U.S. Patent Application No. 60/494,119 filed August 12, 2003, incorporated by reference in its entirety. Power is supplied to air flow generator 20A by battery pack 150 via power cord 110A. Power pack or flow generator may also be integrated into one assembly.

[0049] In one embodiment, air flow generator 20A and battery pack 150 are attached to strap 160 using clips 162A and 162B (see Figure 10B). Of course, this embodiment is not limited to such an attachment system and the air flow generator and/or battery pack may be attached to any suitable part of a wearer's body (including clothing) by any suitable means. For instance, as depicted in Figures 11A and 11B, air flow generator 20A may also be attached to a wearer's arm using, e.g., a Velcro® strap 160A. The motor assembly, including the impeller, may also be attached to other portions of the wearer's body, e.g., the chest via a strap, the shoulder, etc.

[0050] In yet another variant (not shown), the motor assembly may be mounted or provided or combined to a headgear system, with short tubing running to the mask. The headgear system could act as form a of vibration damping. Motors invariably vibrate due to imbalances or during motion. Isolating this vibration from the wearer will reduce irritation and noise. As the head is sensitive to vibration, some form of motor and/or impeller isolation is preferable. A damping system may be used; for example a visco-elastic/soft foam "cushion" between the head and flow generator would provide some benefit.

[0051] In another aspect, a motor can provide a heat sink to provide ability to warm patient breathing air temperature to improve breathing comfort. An additional

aspect is to be able to control the temperature based on ambient conditions, e.g., using a feedback loop. These aspects may be incorporated as part of any of the above embodiments.

[0052] While the invention has been described by way of illustrative embodiments, it is understood that the words which have been used herein are words of description, rather than words of limitation. Changes may be made without departing from the scope and spirit of the embodiments. For example, while embodiments have been described as relation to CPAP application, it is to be understood that the features described herein may also have application in the general ventilation or respiratory arts. In addition, the system can be used for children and adults of all ages.